Instrument Makar, Inc.

NOV 1 5 2000

Litwin Cruciate Anchor 10/25/00 K002600

Accept No Compromise

510(k)Summary

For

Litwin Cruciate Anchor™ (LCA for the ACL™)

LT106100 Ligament Anchor Device

By

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K002600

Trade Name: Litwin Cruciate Anchor

Common Name: Metal bone fixation screw for ligament attachment

Classification: metal internal fixation device

Comparison to Predicate Device

The predicated device is the Instrument Makar, Inc Ligament Capsular Repair ("LCR") Staple. This staple is FDA approved with K 830455. The "LCR" staple is used to hold hamstring tendon loop in the crotch of the staple while the tines are driven into the cancellous bone of the socket for fixation.

The "LCA" is used in the same operation; i.e. anterior cruciate ligament reconstruction, fixation in cancellous bone a bony tunnel of the femur, and securing a loop of hamstring tendon within the eyelet of the screw.

The principle difference in the devices is the design that influences the means of holding the tendon and the device's fixation to bone. The tendon is held in the crotch of the staple. The staple has fixation by two longitudinal tines with "teeth". The tendon is held in the loop on the screw. The screw fixation is by means of the transverse tines.

The devices differ only in their geometry and therefore their means of fixation into bone. The predicate device is a staple and the applicant device is a screw with a loop on the end as illustrated in Appendix A and C. The hamstring tendons are looped under the arch of the staple in contrast to being looped through the eyelet of the LCA™ screw.

Therefore the single issue would be the comparison of the fixation in cancellous bone of the new screw device compared to the predicate device, the IMI staple. Laboratory testing showed the applicant screw device to have better fixation in cancellous bone than the staple as documented in Appendix C.

K00 2600

Description of the Device

Design: The Litwin Cruciate Anchor™ is a metal* cancellous bone screw with an eyelet on one end as illustrated in Appendix A and E.

The screw is designed to hold a loop of hamstring tendon in place in a tunnel of cancellous bone of the femur. The diameter was determined to facilitate placement within a customary 1.0-cm bone tunnel. The length was determined such that it would be contained within the customary surgical tunnel depth of 2.0 to 2.5 cm. The screw mechanism was chosen, as the resistance to movement was probably better than a staple and subsequently substantiated as documented in Appendix C. The tine size and the length of the screw were chosen to optimize the holding characteristics in cancellous bone within the confines of the surgically created bony socket.

*The material in the Instrument Makar, Inc. staple is 316 stainless steel. The material in the LCA™ device as cited in the ASTM F -138-97 is wrought 18 Chromium-14 Nickel-2.5 molybdenum Stainless steel bare and wire for surgical implants (UNS S-31673)

Indications and Intended Use

The indications for use is in patients undergoing anterior cruciate ligament reconstructive surgery due to functional instability of their knee resulting from anterior cruciate ligament tear, acute or chronic. Physical examination and arthroscopic observation should confirm the clinical impression.

The specific intended use of the LCA™ screw device is for fixation of a hamstring tendon graft into a surgically created bone socket (drill hole) on the femoral side during anterior cruciate ligament reconstruction. Intended use is only by qualified experienced orthopedic surgeons familiar with the surgical procedure.

INDICATIONS for the procedure are: tear of the ACL with clinical signs of functional instability, confirmation by physical exam of ACL deficiency, and arthroscopic diagnostic confirmation of torn or absent ACL. Practically the indications for the use of the anchor are the same as for any other fixation device of torn ACL.

CONTRAINDICATIONS are: septic knee, no functional instability, arthritic changes of the involved knee with severe limitation of motion.

Litwin ACL

K002602

POTENTIAL COMPLICATIONS: sepsis, bleeding, loosening of the neuro-vascular injury.

Technological Characteristics

There no specific technological characteristics besides those of the geometry differences between this and the predicate device.

Similarities: Both devices are made of stainless steel. The are similar in size. They have the same purposes during anterior cruciate knee ligament surgery. Both are used to attach the substitute hamstring tendons in a cancellous bone socket or tunnel in the femoral side of the knee joint during anterior cruciate reconstructive surgery. Both devices are commonly implanted under arthroscopic control by experienced orthopedic surgeons. Both devices secure the hamstring tendons in a similar fashion by looping them through the device. The hamstring tendons are looped under the arch of the staple in contrast to being looped through the eyelet of the LCA™ screw.

Single Difference: The devices differ only in their geometry and therefore their means of fixation into bone. The predicate device is a staple and the applicant device is a screw with a loop on the end. (Appendix A and C)

Summary List

Intended use: Fixation of hamstring tendon to bone.
Indications for use: Fixation of tendon graft loop inside tunnel or socket of femoral side of the knee.
Target population: patients with functional instability due to tears of anterior cruciate knee ligament.
Design: Screw with an eyelet.
Materials: Wrought 18 Chromium, 14 Nickel/2.5 Molybdenum stainless steel
Performance: enhanced fixation over the predicate device established by laboratory testing.
Sterility: delivered to end user as NOT STERILE
Biocompatibility: known and accepted for stainless steel
Mechanical safety: Established by steel material, design and testing.
Chemical safety: N/A
Anatomical sites: Knee joint.

Litwin ACL

K002600

Human factors: None for the recipient. Intended for use by licensed physician and surgeon, specializing in orthopedic surgery with knowledge and experience in ligament reconstruction of the knee.
Energy used: N/A
Compatibility with environment: yes
Where used: Standard operating room for knee joint surgery.
Standards met: Yes
Electrical safety: N/A
Thermal safety: N/A
Radiation safety: N/A

Assessment of non-clinical performance data

Instron testing was performed at the Laboratory of Comparative Orthopaedics, College of Veterinary Medicine, Michigan State University East Lansing, MI

The resistance to device pullout from cancellous bone was performed by Instron Machine. The hypothesis was that the Litwin ACL screw would have greater resistance to pull out than the predicate IM Staple device. The hypothesis was confirmed. The screw had significantly greater resistance to pullout from cancellous bone, the anticipated host tissue type.

No clinical assessment was made.

Conclusions: The Litwin ACL screw would have similar function in ACL ligament reconstruction as the predicate device, the IM Screw, but with better security to the bone. The indications, contraindications, surgical technique, surgeon's experience, and post operative care would be similar for both devices with the Litwin ACL screw more likely to resist fixation failure in the host tissue, cancellous bone. The LCA™ screw is a substantial equivalent of the Instrument Makar, Inc. Metal Staple (K 830455), a Class II device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2000

Lanny Johnson, M.D.
Instrument Makar, Inc.
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Okemos, Michigan 48864

Re: K002600
Trade Name: Litwin Cruciate Anchor (LCA)
Regulatory Class: II
Product Code: MBI, HWC
Dated: August 17, 2000
Received: August 21, 2000

Dear Dr. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R. Ogden for

Célia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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(Division Sign-Off) MAO for CMW
Division of General Restorative Devices
510(k) Number K002600

Prescription Use only
(Per 21 CFR 801.109)